

K063745

Appendix A

APR 23 2007

510 (k) Premarket Notification Summary
(Per 21 CFR 807.92)

MediLaser System

- I. Applicant
Laser Thera, LLC
Shelly Henry, President
11108 Ashford Drive
Yukon OK 73099
- II. Device Name:
Proprietary Name: MediLaser
Common/Usual Name: Infrared lamp
Classification Name: Infrared lamp (21 CFR 890.555)
Product Code: ILY
- III. The MediLaser System is substantially equivalent to other infrared lamps currently in commercial distribution such as the Thor IR Lamp System/ Super Nova/ Acubeam systems.
- IV. Intended use of the Device
The MediLaser is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, for the temporary relief of minor joint pain associated with arthritis, for the temporary increase in local circulation where applied and the relaxation of muscles.
- V. Description of Device
The MediLaser is a portable, hand held, AC operated non-invasive, low level infrared lamp that provides continuous heat therapy at a fixed frequency.
- VI. Summary of the technical characteristics of the MediLaser
The MediLaser and the aforementioned predicate devices are an infrared lamp as defined in 21 CFR 890.5500. These devices utilize infrared diodes to generate topical heating for the purpose of elevating tissue temperatures for the temporary relief of minor muscle and joint pain and stiffness, minor arthritis pain, or muscle spasm, the temporary increase in local circulation and the temporary relaxation of muscle. The systems are intended to be placed directly on the skin to provide heating.
- VII. Testing
Testing of the MediLaser included functional performance testing and electrical safety testing.

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VIII Software Verification and Validation – No software is required to operate the device.

IX Conclusions

Pursuant to the testing and comparison to the predicate devices, the MediLaser has the same intended uses, with similar functional and performance characteristics. The MediLaser is designed to comply with the general accepted therapeutic heat performance specifications by producing a level of tissue temperature reported in literature and accepted by the Federal Food and Drug Administration.

The MediLaser performs as intended and do not raise any new safety or efficacy issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Laser Thera, LLC
% Ms. Shelly Henry
5300 N. Meridian, Suite 1
Oklahoma City, Oklahoma 73112

APR 23 2007

Re: K063745
Trade/Device Name: MediLaser
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared lamp
Regulatory Class: II
Product Code: ILY
Dated: March 9, 2007
Received: March 9, 2007

Dear Ms. Henry:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

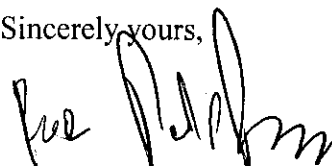
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Shelly Henry

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", written over the typed name.

Mark N. Melkerson

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: MediLaser

Indications For Use:

The MediLaser is an infrared lamp that is intended to emit energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for the temporary relief of minor muscle and joint pain and stiffness, for the temporary relief of minor joint pain associated with arthritis, for the temporary increase in local circulation where applied and the relaxation of muscles.



(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number

16063798

Prescriptions Use x
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER
PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)